

### REMARKS

The Office Action of October 11, 2005 has been received and reviewed. Claims 1, 3-5, 7, 9, 10, 12-19, 21, and 24-47 are currently pending. Claims 7, 13, 25-28, 35-37, and 39-41 have been withdrawn from consideration. New claims 42-47 have been added herein. Claims 10, 15, 18, 21, 24, 31, 32, and 34 have been cancelled. Claims 1, 14, 16, 17, 19, 33, and 38 have been amended. Claims 1, 3-5, 9, 10, 12, 14-19, 21, 24, 29-34, and 38 stand rejected. All amendments and claim cancellation are made without prejudice or disclaimer. Reconsideration is respectfully requested.

#### Claim Objections

Claim 38 is objected to as assertedly “providing a kit comprising nucleic acids comprising SEQ ID NOS: 72 and 81 and/or proteinaceous molecules capable of specifically binding to SialoAdhesin or TIE-1.” *Office Action* at page 3. Further, the Examiner alleges that “claim 38 is objected to because it containing subject matter that was not elected by original presentation and will be examined to the extent is applies to the elected subject matter.” *Id.*

Although the applicants do not agree with the Examiner’s interpretation of claim 38, to expedite prosecution, claim 38 has been amended. As amended, claim 38 no longer recites “and/or proteinaceous molecules capable of specifically binding to SialoAdhesin or TIE-1.” As such, applicants respectfully assert that claim 38 is no longer rejected to subject matter that was not previously elected. Consequently, applicants respectfully request withdrawal of the objection to claim 38 and reconsideration of the same.

#### Rejections under 35 U.S.C. § 112, second paragraph

Claims 19, 33, 34, and 38 stand rejected under 35 U.S.C. § 112, second paragraph, as assertedly being indefinite for failing to particularly point out and distinctly claim the subject matter which the applicants regard as the invention. Applicants respectfully traverse the rejections as hereinafter set forth.

Applicants respectfully note that the rejection of claim 34 is moot as claim 34 has been cancelled herein.

As indicated in the Office Action, it was thought that the final process of steps of claims 19, 33, and 38 are not within the scope of the preamble. *Id.* at page 4. Specifically, the Examiner asserts that claims 19, 33 and 38 are “indefinite as to whether the claims are intended to be limited to methods of determining a Kaposi’s Sarcoma tumor cell as referred to in the preamble or a method of determining any tumor cell.” *Id.*

Although the applicants do not agree with the Examiner’s interpretation of claims 19, 33, and 38, to expedite prosecution, claims 19, 33, and 38 have been amended. Specifically, claims 19, 33, and 38 have been amended to recite “indicates the presence of a Kaposi’s Sarcoma tumor cell” in the final method step. As such, applicants respectfully submit that, as amended, the claims are clearly directed to methods of determining the presence of a Kaposi’s Sarcoma tumor cell. Consequently, applicants respectfully request withdrawal of the rejections under 35 U.S.C. § 112, second paragraph, of claims 19, 33, and 38 and reconsideration of the same.

#### **Rejections under 35 U.S.C. § 112, first paragraph**

##### **A) Rejection of claims 19 and 34 as assertedly lacking written description**

Claims 19 and 34 stand rejected under 35 U.S.C. § 112, first paragraph, as assertedly failing to comply with the written description requirement. Applicants respectfully traverse the rejections as hereinafter set forth.

Applicants respectfully note that the rejection of claim 34 is moot as claim 34 has been cancelled herein.

As indicated in the Office Action, it was thought that “the skilled artisan would not know which sequences fall within the large genus of the sialoadheson and TIE-1 expression encompassed by the recitation of the claims.” *Id.* at page 7. Although the applicants do not agree with the Examiner’s interpretation of claim 19, to expedite prosecution, claim 19 has been amended. Specifically, claim 19 has been amended to provide specific genbank accession numbers for Siglec-1 (a Sialoadhesin) and TIE-1. Basis for the amendments can be found throughout the specification. Specifically, Siglec-1 and the corresponding accession number can be found at page 37, line 19 of the as filed specification and basis for the TIE-1 accession number

can be found at page 34, line 24 of the as filed specification. As such, one of skill in the art would be readily by able to determine which sequences fall within the claims. Consequently, applicants respectfully request withdrawal of the rejection under 35 U.S.C. § 112, first paragraph, of claim 19 and reconsideration of the same.

**B) Rejection of claims 1, 3-5, 9, 10, 12, 14-19, 21, 24, 29-34, and 38 as assertedly lacking enablement**

Claims 1, 3-5, 9, 10, 12, 14-19, 21, 24, 29-34, and 38 stand rejected under 35 U.S.C. § 112, first paragraph, as assertedly failing to comply with the enablement requirement. Applicants respectfully traverse the rejections as hereinafter set forth.

Applicants respectfully note that the rejections of claims 7, 10, 15, 18, 21, 24, 31, 32, and 34 are moot as these claims have been cancelled herein.

As indicated in the Office Action, it was thought that it is not taught how much change in the expression level of SEQ ID NO 72 or 81 indicates the presence of a Kaposi's Sarcoma tumor cell or angiogenesis. Furthermore, the Examiner alleges that the specification does not indicate how a change in expression of SEQ ID NO 72 or 81 relates to the efficiency of a treatment.

Although the applicants do not agree with the Examiner's characterization of the claims or the specification, claims 1, 14, 16, 17, 19, 33, and 38 have been amended to expedite prosecution. Basis for the amendments to claims 1, 14, 16, 17, 19, 33, and 38 can be found throughout the specification and more specifically in Examples 2-7 and Tables 1-4.

Specifically, claims 1, 16, and 17 have been amended to recite that "wherein at least a two fold reduction indicates that said treatment is effective ...." As such, applicants respectfully submit that claims 1, 16, and 17, as amended, clearly recites how much change in the expression level of SEQ ID NO 72 or 81 indicates the efficacy of a treatment in counteracting the status of Kaposi's tumor cells in an individual.

As to claims 14, 19, 33, and 38, these claims have been amended, in regards to Siglec -1 and TIE-1 or SEQ ID NOS 72 and 81, to recite "wherein at least two fold overexpression indicates the presence of a Kaposi's tumor cell." As such, applicants respectfully submit that claims 14, 19, 33, and 38, as amended, clearly recite how much change in the expression level of the sequences recited indicates the presence of a Kaposi's tumor cell.

In addition, the Examiner alleges that the specification does not provide a working example or a detection expression level to determine angiogenesis using the markers SEQ ID NOS 72 or 81. Although the applicants respectfully disagree with the Examiner's interpretation of the specification, to expedite prosecution, references to angiogenesis have been deleted from the currently pending claims.

Last, in regards to enablement in general, it is required that the disclosure contains sufficient information to enable one skilled in the pertinent art to make and use the claimed invention. MPEP § 2164.01. Applicants respectfully submit, that the disclosure, coupled with the high level of skill in the art (see *Office Action*, mailed October 11, 2005, at page 16), allows one to make and use the invention as defined by the claims without undue experimentation.

Specifically, given that specific sequences are provided and claimed, it is well within the high level of skill in the art, using the guidance of the specification, to determine relative levels of expression. Further, as specific sequences and indicative changes in their expression are provided in the claims, applicants respectfully submit that little or no experimentation would be required to make and use the claimed invention. As such, applicants respectfully submit that the claims are enabled under 35 U.S.C. § 112, first paragraph.

In light of the above amendments and remarks, applications respectfully submit that the claims 1, 12, 14, 16, 17, 19, 33, and 38, as amended, are enabled. Consequently, applicants respectfully request withdrawal of the rejections of claims 1, 12, 14, 16, 17, 19, 33, and 38 under 35 U.S.C. § 112, first paragraph and reconsideration of the same. Further, as claims 3-5, 9, 29, and 30 depend directly or indirectly from claims 1, 19, 33, and 38, applicants respectfully submit they are allowable, *inter alia*, as depending from an allowable base claim.

### **Non-Statutory Double Patenting**

Claims 1, 3-5, 9, 12, 14-19, 22, 24, 31-24, and 38 are provisionally rejected as assertedly violating the judicially created doctrine of obvious type double patenting in view of the claims of U.S. Patent Application 10/310,677. Applicants assert that if the current provisional non-statutory double patenting rejection ever ripens, the claims of the remaining application will be amended to remove the non-statutory double patenting rejection or that a terminal disclaimer will be filed.

**CONCLUSION**

In light of the above amendments, claim cancellations, and remarks, applicants respectfully request reconsideration of the application. If there are any questions concerning the foregoing, or if the Office should determine that there are additional issues which might be resolved by a telephone conference, the Examiner is respectfully invited to contact the applicants' undersigned attorney.

Respectfully submitted,



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